



Guidelines for Medical Necessity Determination for Capsule Endoscopy

This edition of Guidelines for Medical Necessity Determination (Guidelines) identifies the clinical information that MassHealth needs to determine medical necessity for capsule endoscopy. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at [130 CMR 433.000](#): *Physician Services* and [130 CMR 450.000](#): *Administrative and Billing Regulations*, and [Subchapter 6](#) of the Physician Manual, for information about coverage, limitations, service conditions, and prior-authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care organization, Senior Care Options (SCO), or Program of All-Inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care Organization's, SCO's, or PACE's medical policies, respectively, for covered services.

MassHealth requires PA for capsule endoscopy and reviews PA requests on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

SECTION I. GENERAL INFORMATION

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Capsule endoscopy (CE) consists of the placement of a capsule with Federal Drug Administration (FDA) approval for imaging the lumen of the gastrointestinal (GI) tract. CE is used primarily as an adjunctive test to determine the etiology and/or location of "obscure GI bleeding," defined as bleeding of unknown origin that persists or recurs after initial negative esophagogastroduodenoscopy (EGD) and colonoscopy. CE may also be used in the diagnosis of Crohn's disease or for the identification of previously undocumented lesions in polyposis syndromes. These guidelines pertain to outpatient use of CE, and are targeted to the evaluation of GI bleeding that is occult, or intermittently overt, rather than active. Therefore, use of CE in active GI bleeding in hospitalized patients is not included in these guidelines. The PA request is for placement of a capsule to determine the etiology of obscure GI bleeding, the diagnosis of Crohn's disease, or for identifying small bowel lesions that may not be apparent using other screening methods.

MassHealth considers approval for coverage of CE on an individual, case-by-case basis, in accordance with 130 CMR 433.000 and 130 CMR 450.204, when needed to either diagnose or locate lesions whose identification may result in a change in therapy or initiation of a new therapy for the individual.

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SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for CE on clinical data, including, but not limited to, indicators that would affect the relative risks and benefits of the procedure. These criteria include, but are not limited to, the following.

1. The member must have at least one of the following:
 - a. obscure GI bleeding;
 - b. known or suspected Crohn's disease;
 - c. a polyposis syndrome or suspected small intestinal tumors;
 - d. an unexplained iron-deficiency anemia *and* one of the following:
 - suspected obscure GI bleeding with a documented positive fecal occult blood test;
 - iron deficiency anemia refractory to iron supplementation;
 - risk factors for small bowel vascular pathology (e.g., patients with aortic stenosis or chronic kidney disease have propensity for small bowel arteriovascular malformations);
 - enterography suggesting a small bowel tumor; or
 - identification of a bleeding lesion for prognostic or management purposes (e.g., the use of anticoagulation or antiplatelet medications);
 - e. refractory celiac disease in a patient adherent to dietary changes.

Members without at least one of the conditions listed above will be considered for approval on an individual basis.

Note: CE has a relative contraindication in pregnancy because there exists limited safety data for the fetus if the capsule must be retrieved endoscopically. CE may be approved in urgent cases in which endoscopy cannot be delayed until after delivery.

2. The member has no evidence from the medical history and other evaluations of the GI tract that could account for the problems that the CE is intended to identify.
3. The results of the CE must be likely to influence therapeutic decisions about the member's care. For example, if a CE study is performed with the belief that a positive finding will require a surgical intervention, then the member must be a likely surgical candidate at the time of the CE study.
4. The CE procedure must conform to FDA approved indications for the particular capsule being used.
5. The images will be interpreted by a gastroenterologist.
6. These guidelines apply to duodenal and small intestinal CE. PA requests for esophageal or colonic capsule endoscopy require additional documentation of medical necessity including, but not limited to, documentation of contraindication for EGD or colonoscopy.

B. NONCOVERAGE

MassHealth does not consider CE to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following:

1. Studies for experimental or investigational purposes;
2. CE used for initial or screening evaluations;
3. CE for the purpose of monitoring the course of celiac disease after diagnosis without other indications;
4. Conditions for which CE is contraindicated, including, but not limited to, known or suspected GI obstruction or stenosis;
5. Colonic CE;
6. To make an initial diagnosis of celiac disease;
7. Abdominal pain in the absence of gastrointestinal bleeding; and
8. To diagnose Barrett's esophagus.

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SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA for CE must be accompanied by clinical documentation that supports the medical necessity for this procedure.

- A. Documentation of medical necessity must include all of the following:
 1. The primary diagnosis name and current International Classification of Diseases-Clinical Modification (ICD-CM) code pertinent to the clinical symptoms;
 2. Secondary diagnosis name(s) and current ICD-CM code(s) pertinent to comorbid condition(s);
 3. A summary of the medical and surgical history;
 4. If the CE is being performed for the evaluation of obscure GI bleeding, evidence of substantial GI bleeding and/or lab results supporting the presence of iron-deficiency anemia (occult-blood positive stool without iron-deficiency anemia is not, by itself, sufficient evidence.);
 5. Report of colonoscopies that were performed within two years of the PA request;
 6. Documentation for evaluation of the upper-GI tract, which varies depending on the following clinical considerations:
 - a. For obscure GI bleeding: Results of an upper-GI tract evaluation performed within two years of the PA request for CE, including EGD, unless medically contraindicated.
 - b. For initial diagnosis of suspected Crohn's disease: One upper-GI tract evaluation, including computed tomography (CT) enterography, and/or upper gastrointestinal (UGI) series with small bowel follow-through;

7. For subsequent (including post-op) evaluation of already-diagnosed Crohn's disease: a description of any current therapy, and what changes in therapy are anticipated if CE is positive for Crohn's lesions;
 8. Documentation of the most recent physical exam; and
 9. Any other pertinent information that MassHealth may request.
- B. Clinical information must be submitted by the gastroenterologist who will be performing the CE study. *Providers are strongly encouraged to submit requests electronically.* Providers must submit all information pertinent to the diagnosis using the [Provider Online Service Center \(POSC\)](#) or by completing a MassHealth Prior Authorization Request form (using the [PA-1](#) paper form found at www.mass.gov/masshealth) and attaching pertinent documentation. The PA-1 form and documentation should be mailed to the address on the back of the form. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900, TDD/TTY: 711.

Select References

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Appendix

APPLICABLE CPT® CODES

The Current Procedural Terminology (CPT®) code provided below is for informational purposes only. CPT® coding is the sole responsibility of the billing party. Inclusion of a CPT® code in these Guidelines does not imply that the service described by this code is a covered service. This list of codes may not be all-inclusive.

CPT® Code	Description
91110	Duodenal and small intestinal CE

CPT® is a registered trademark of the American Medical Association.

These Guidelines are based on review of the medical literature and current practice in capsule endoscopy. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment. Some language used in this communication may be unfamiliar to other readers; in this case, such readers should contact their health care provider for guidance or explanation.

Policy Revision Effective Date: 5/3/2023

Approved by: _____



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Policy Effective Date: 6/1/2018